

REMARKS

Claims 1, 3, 4, 6-17, and 21-27 are pending. Claims 1, 11 and 22 are amended herein to more clearly claim what Applicants consider to be their invention. Claims 1, 3, 4, 6-10 and 27 have been withdrawn as being drawn to a non-elected invention. Claims 11-17 and 21-26 are under consideration. Support for these amendments can be found in the original claim language and throughout the specification, as set forth below. Support can be found in the specification as shown in U.S. Publication No. 20040096410 at least at paragraphs [0021], [0061], [0080], [0082], [0083], [0084], and [0096]. It is believed that these amendments add no new matter. In light of these amendments and the following remarks, Applicants respectfully request reconsideration of this application, entry of these amendments, and allowance of the claims to issue.

Filed herewith is a Request for Continued Examination.

35 U.S.C. § 102

Claims 11-17 and 24-26 remain rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Patent No. 6,143,794 ("Chaudhuri"). Applicants respectfully note that Claims 24-26 depend from Claim 22, which is not anticipated by the cited reference. The Office Action stated that Chaudhuri discloses a topical formulation for the treatment of fungal diseases comprising the

- the flexible membrane of instant Claims 11 and 22 (i.e., semisolid gel) (see col. 4, lines 46-47);
- the hydrophilic polymer matrix of instant Claim 11 (see col. 6, lines 13-45);
- the active agent of instant Claim 11 (see col. 4, line 41);
- the humectant (e.g., polyethylene glycol) of instant Claim 11 (see col. 6, lines 2-12);
- the moisture content of instant Claim 11, i.e., up to 68.4% (see claim 1(h));
- the direct contact with an unguated structure of instant Claim 11 (see col. 9, lines 59-67);
- the organic acid of instant Claim 11 (see col. 4, lines 22-37 – i.e., pharmaceutically acceptable salt of an active compound using, e.g., citric acid);
- the moisture management system (as disclosed in pages 23-24 of the instant specification) of instant Claim 12 (see col. 6, lines 13-45);

- the attachment element (adhesive) of instant Claim 13 (see col. 6, line 49);
- the polyacrylamide of instant Claims 14 and 24-26 (see col. 6, line 22);
- the citric acid of instant Claim 15 (see col. 4, line 34);
- the polyethylene glycol of instant Claim 16 (see col. 6, lines 8-9); and
- the moisture content of instant Claim 17 (see Tables D and E).

Applicants traverse this rejection as it is applied to the claims as amended herein.

For a prior art reference to anticipate a claimed invention, each and every element of the claimed invention must be disclosed in that single reference. Further, the disclosure in that single reference must be enabling. If one element of the claimed invention is not disclosed in the prior art reference, there is no anticipation. It is settled law that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently.” *Verdegaal v. Union Oil*, 814 F2d. 628, 2 USPQ2d 1051 (Fed. Cir. 1987).

Chaudhuri does not teach a composition comprising a solid matrix sheet comprising a hydrophilic polymer matrix. Chaudhuri teaches that “[g]enerally the composition is a liquid or semisolid, such as a cream, ointment, lotion, or gel (preferably a gel) having a solvent in which the antifungal compound, or its salt, is dissolved.” See Col. 4, lines 45-49. Further, Chaudhuri teaches that “[i]n addition to the antifungal compound and a pharmaceutically-acceptable solvent, the composition of this invention also includes a gelling agent in an amount sufficient to form a gel.” See Col. 6, lines 13-15. Because Chaudhuri does not teach each and every element of amended Claims 11 and 22, there is no anticipation. Therefore, Applicants respectfully request withdrawal of this rejection and allowance of amended Claim 11 and dependent Claims 12-17, and dependent Claims 24-26.

35 U.S.C. § 103

Claims 21-23 remain rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,143,794 (“Chaudhuri”). The Office Action stated that Chaudhuri teaches a topical formulation for the treatment of fungal diseases and explains that the disclosed invention provides a gel capable of delivering an antifungal through the nail barrier (see col. 2, lines 14-15). The Office Action stated that while Chaudhuri does not explicitly teach the percentages of instant Claims 21-23, it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine

suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art. See Office Action, page 4, paragraph 3. The Office Action also stated that one of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides a gel capable of delivering an antifungal through the nail barrier, as explained by Chaudhuri.

Applicants traverse this rejection as it is applied to the claims as amended herein.

Claim 21 depends from amended Claim 11 and includes all of the limitations of amended Claim 11. Claim 23 depends from amended Claim 22 and includes all of the limitations of amended Claim 22. Claims 11 and 22 have been amended, and Chaudhuri does not provide a teaching or suggestion of the currently claimed invention that would render Claims 21-23 obvious.

It is the burden of the Office to provide a rationale from the prior art for making the specific claimed modification or combination. The Supreme Court recently addressed nonobviousness of “combination” inventions in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (*KSR*). The Court confirmed that it is legally insufficient to merely point to the various recited elements. Instead, the Office must identify the basis for the alleged modification or combination by one of ordinary skill to arrive at the claimed invention.

As is clear from cases such as *Adams*, a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

KSR at *37-*38 (emphasis by underlining added).

Moreover, the Supreme Court opined that conclusory statements cannot provide an adequate basis for the alleged modification or combination; the reasoning must be explicit.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there

was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) (“Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”). *KSR* at *36-*37 (emphasis by underlining added).

Absent this explicit reasoning to support the basis for the modification or combination, the alleged modification or combination cannot support a *prima facie* obviousness rejection.

The Supreme Court has reaffirmed the Graham factors for determination of obviousness under 35 U.S.C. 103(a) in *KSR*. The four factual inquiries under *Graham* require examination of: (1) the scope and contents of the prior art; (2) the differences between the prior art and the claims in issue; (3) the level of ordinary skill in the pertinent art; and (4) the objective evidence of secondary consideration. *Graham v. John Deere (Graham)*, 383 U.S. 1, 17-18, 149 USPQ 459, 467 (1966); see also 35 U.S.C. § 103 (2000).

The Court has further recognized that the requirement for a teaching, suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, which was established by the Court of Customs and Patent Appeals, provides a helpful insight for determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a). In addition, the Court maintained that any analysis supporting a rejection under 35 U.S.C. § 103(a) should be made explicit, and that it is “important to identify reasons that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed, because “inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR* at 14, 15.

Further, courts have generally recognized that a showing of a *prima facie* case of obviousness necessitates three requirements: (i) some suggestion or motivation, either in the references themselves or in the knowledge of a person of ordinary skill in art, to modify the reference or combine the references’ teachings; (ii) a reasonable expectation of success; and (iii) the prior art references must teach or suggest all of the claim limitations. See e.g., *In re*

Dembiczak, 175 F.3d 994 (Fed. Cir. 1999); *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

The Office has failed to make a *prima facie* case of obviousness. As argued above, Chaudhuri does not teach each and every element of amended Claims 11 and 22, nor does Chaudhuri render Claims 21-23 obvious for the following reasons.

Chaudhuri does not teach or suggest a composition comprising a solid matrix sheet comprising a hydrophilic polymer matrix. Not only does Chaudhuri not teach or suggest the currently claimed invention, Chaudhuri teaches away from the claimed invention. Chaudhuri teaches that “[g]enerally the composition is a liquid or semisolid, such as a cream, ointment, lotion, or gel (preferably a gel) having a solvent in which the antifungal compound, or its salt, is dissolved.” See Col. 4, lines 45-49. Further, Chaudhuri teaches that “[i]n addition to the antifungal compound and a pharmaceutically-acceptable solvent, the composition of this invention also includes a gelling agent in an amount sufficient to form a gel.” See Col. 6, lines 13-15.

Applicants are not arguing for a rigid application of the teaching-suggestion-motivation (TSM) rationale, which requires that a printed statement be present for a finding of obviousness. Instead, Applicants submit that the Supreme Court acknowledged that the TSM test was one of a number of valid rationales that could be used to determine obviousness. *KSR* at 1727 (2007); see MPEP 2141; *In re Kahn*, 441 F.3d 977, 986, 78 U.S.P.Q. 2d 1329, 1335 (Fed. Cir. 2006). Applicants respectfully submit that there is no suggestion or motivation to make the proposed modification of an antifungal composition taught in Chaudhuri to make the claimed invention.

Modification of the antifungal composition taught in Chaudhuri, i.e., a liquid or gel, to create an antifungal composition of the currently pending claims would render the Chaudhuri patent unsatisfactory for its intended purpose. According to the U.S. Court of Appeals for the Federal Circuit, “[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed invention.” (*In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 125 (Fed. Cir. 1984); see MPEP 2143.01).

A person of ordinary skill in the art, at the time the instant application was filed, would not be motivated to modify the teachings of Chaudhuri to create the claimed invention. Thus, independent 22 is not obvious. Moreover, dependent Claims 21 and 23 are not obvious as Claim

11 from which they depend, was not rejected as obvious. See *In re Fine*, 5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988) (“Dependent claims are non-obvious under section 103 if the independent claims from which they depend are non-obvious.”).

Claims 21-23 are not obvious in view of the disclosure of Chaudhuri. Therefore, Applicants respectfully request withdrawal of this rejection and allowance of amended independent Claim 22 and Claims 21 and 23, which depend from Claim 11.

CONCLUSION

The foregoing is a complete response to the Office Action dated December 3, 2009. Applicants respectfully submit that Claims 11-17 and 21-26 are patentable. Early and favorable consideration is solicited. Rejoinder of the withdrawn claims is also requested.

Applicants file this response solely to facilitate prosecution. As such, Applicants reserve the right to pursue claims of broader or similar scope as originally filed in a continuation application or other application after allowance of the present application. Applicants do not concede that the current or past rejections are correct and reserve the right to challenge such rejections later in prosecution or on appeal. Accordingly, any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending claims are believed to be warranted, and such action is respectfully requested. The Examiner is invited to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issuance.

A credit card payment submitted via EFS Web in the amount of \$1,300.00 (representing \$810.00 for the fee for a large entity under 37 C.F.R. § 1.17(e) and \$490.00 for the fee for a large entity under 37 C.F.R. § 1.17(a)(2)), a Request for Continued Examination, and a Petition for Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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